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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,286	02/03/2005	Christopher J. Dinsmore	21007YP	3804
210	7590	06/11/2007		
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			EXAMINER CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,286	Applicant(s) DINSMORE ET AL.	
	Examiner Yong Chu	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 7-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 1-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/09/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3 have been amended in the reply on 03/29/2007. Claims 1-19 are pending. Claims 7-19 are non-elected claims. Therefore, Claims 1-6 are subject for examination on the merits.

Information Disclosure Statement

Applicants' Information Disclosure Statement, filed on 11/08/2006, has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

Response to Amendment

The amendment by Applicants' representative Dianne Brown, dated on 03/29/2007 has been entered.

Response to Arguments

Argument over Restriction Requirement

Applicants argue that all claims of the instant application (e.g. Group I-III) should be examined together because all the subject matters can be searched together without serious burden to the examiner. This argument has been considered and is found not persuasive, because the inventions of Groups I-III are independent or distinct for the reasons given in the previous Office action dated on 05/05/2006 and require different search and examinations in different fields under different classifications and STN search strategies. There would be a serious burden on the examiner if the restriction were not required. Rejoining Groups I, II and III might be possible if Group I is found allowable and certain conditions are met.

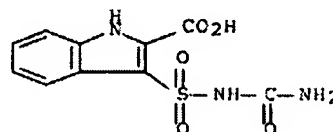
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Argument over rejection of claims 1-5 under 35 U.S.C. §112, second paragraph

The rejection of claims 1-3 and 6 under 35 U.S.C. §112, second paragraph for mutually dependent R³ and R⁷ has been withdrawn, because Applicant has amended the claims, and the rejection was overcome.

Rejection of claims 1-3, and 6 under 35 U.S.C. §102

Applicant's argument over rejection of claims 1-3, and 6 under 35 U.S.C. §102(b) as being anticipated by the '875 patent has been considered, and is found persuasive. The Examiner agrees with Applicant's argument that the



examiner cited compound (CAS RN 875830-38-9) is not disclosed in the '875 patent, even though was indicated in the STN search report. Therefore, the rejection has been withdrawn.

The rejection of claims 1-3 and 6 under 35 U.S.C. §102(b) as being anticipated by the Szmuszkovic JOC article is obviated by the amendment of claims 1-3 and 6 to exclude R⁵ as hydrogen.

Rejection of claims 1-3, and 6 under 35 U.S.C. §103(a)

The rejection of claims 1-3, and 6 under 35 U.S.C. §103(a) as being unpatentable over the Szmuszkovic JOC article is obviated by the amendment of claims 1-3 and 6 to exclude R⁵ as hydrogen. Since the JOC article does not suggest any utility, the rejection is withdrawn.

Claims 1-3 and 6 were amended by Applicant. According to MPEP §803.02, the search has been expanded and new art applied.

Claim Rejections - 35 USC § 102(b)

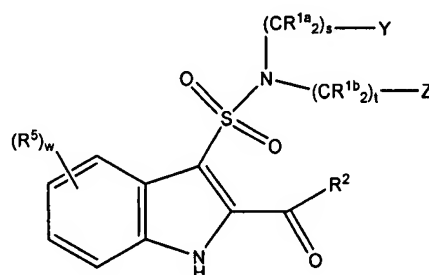
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6 are rejected under 35 U.S.C. 102 (b) as being anticipated by Williams et al., U.S. Patent 5,527,819 (the '819 patent).

Applicants' instant elected invention in claims 1-3, and 6 teach a



compound of formula (I), , depicted in claim 1, and their pharmaceutically acceptable salts and pharmaceutical composition thereof wherein:

R^{1a} and R^{1b} are independently selected from hydrogen, unsubstituted and substituted C_1 - C_{10} alkyl;

R^{1c} is independently selected from: hydrogen, and C_1 - C_{10} alkyl; said alkyl, is optionally substituted with at least one sunstituent selected from R^7 ;

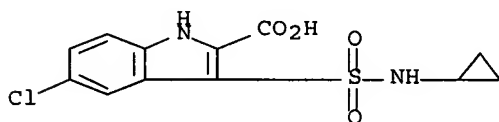
R^2 is independently selected from $N(R^3)_2$, and OR^3 ;

R^3 is independently selected from hydrogen and C_1 - C_{10} alkyl; said alkyl, is optionally substituted with OR , wherein R is H or C_1 - C_{10} alkyl;

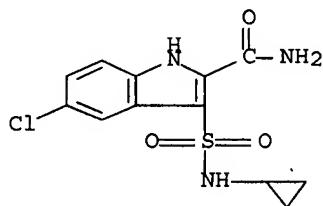
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 R^5 is halogen, R^6 is independently selected from C_1 - C_{10} alkyl and C_3 - C_{10} cycloalkyl; said alkyl, cycloalkyl is optionally substituted with at least one substituent selected from R^7 ; Y is H, R^6 , or $S(O)_mN(R^3)_2$; Z is H; s is 0 to 6; t is 0 to 6; m is 2; n is 0 to 6; w is 0 to 4, and the remaining substituents are defined in claim 1

The '819 patent disclose specific compounds



(CAS CN 158561-85-4), see line 47-48



column 67, and

(CAS CN 158561-72-9, Example 68),

see line 55-56 column 66. These prior art compounds anticipate the instantly claimed genus.

Since the compounds are anticipated, the pharmaceutical composition comprising the claimed compound is also anticipated.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

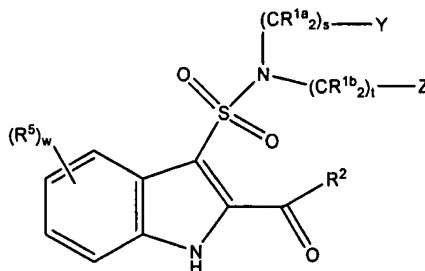
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103 (a) as unpatentable over Williams et al., U.S. Patent 5,527,819 (the '819 patent).

Applicants' instant elected invention in claims 1-3, and 6 teach a



compound of formula (I), , depicted in claim 1, and

their pharmaceutically acceptable salts and pharmaceutical composition thereof

wherein:

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R^{1a} and R^{1b} are independently selected from hydrogen, unsubstituted and substituted C_1 - C_{10} alkyl;

R^{1c} is independently selected from: hydrogen, and C_1 - C_{10} alkyl; said alkyl, is optionally substituted with at least one substituent selected from R^7 ;

R^2 is independently selected from $N(R^3)_2$, and OR^3 ;

R^3 is independently selected from hydrogen and C_1 - C_{10} alkyl; said alkyl, is optionally substituted with OR , wherein R is H or C_1 - C_{10} alkyl;

R^5 is halogen,

R^6 is independently selected from C_1 - C_{10} alkyl and C_3 - C_{10} cycloalkyl; said alkyl, cycloalkyl is optionally substituted with at least one substituent selected from R^7 ;

Y is H, R^6 , or $S(O)_mN(R^3)_2$;

Z is H;

s is 0 to 6;

t is 0 to 6;

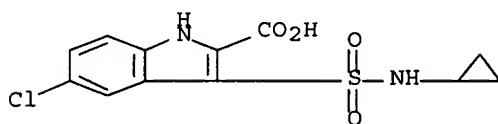
m is 2;

n is 0 to 6;

w is 0 to 4, and the remaining substituents are defined in claim 1

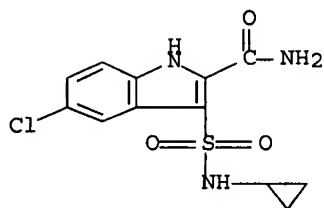
Determination of the scope and content of the prior art (MPEP §2141.01)

The '819 patent disclose specific compounds



(CAS CN 158561-85-4), see line 47-48

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column 67, and

(CAS CN 158561-72-9, Example 68),

see line 55-56 column 66. The prior art compounds or composition is claimed for pharmaceutical utilities, such as treating cancer.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '819 patent and the instantly claimed compounds, is R^5 is -Cl for the prior art compound, and -Br for the instantly claimed compounds.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in the chemical art, one homologue is not such an advance over replacement of -Br with -Cl, which is suggested by claim 1 of the '819 patent that X as -Cl, Br, and -F are exchangeable. The instant claimed compounds would have been obvious, because one skilled in the art would have been motivated to prepare the compounds taught in the reference with the expectation of obtaining compounds which could be used in the related compounds or composition for pharmaceutical applications. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claim Objections

Claims 1-6 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

Conclusion

- Claims 1-6 are rejected.
- Claims 1-6 are objected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiry

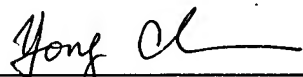
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699.


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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Yong Chu, Ph.D.
Patent Examiner
Art Unit 1626



REBECCA ANDERSON
PATENT EXAMINER



Joseph K. McKane
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